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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,959	06/27/2003	David F. Nicoli	6000	4840

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,959

Applicant(s)

NICOLI ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

1. Claims 40-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 7-8 of claim 40, the phrase "the height of said inter-particle potential energy barrier" lacks antecedent basis. See this same problem on lines 8-9 of claim 47. On line 10 of claim 40, the phrase "the increase in said agglomeration" lacks antecedent basis.

On lines 1-2 of claim 67, the phrase "said means supplying said stress factor" lacks antecedent basis since independent claim 47 recites means for applying a stress factor.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 8, 47 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Garver et al. (US Patent no. 6,263,725, submitted in the Information Disclosure Statement filed on September 24, 2003)

Garver et al teach of a method and apparatus for characterizing the stability of colloids (i.e. dispersions of solid or liquid particles suspended in a liquid carrier) by applying a stress factor to a sample of a colloid, and measuring the light attenuation or scattering of the sample at two or more wavelengths. The stress factor applied to the colloid is a change of temperature. The light attenuation or light scattering is measured at two or more temperatures to provide a measure of the stability of the dispersion with respect to temperature. The amount of certain colloids that are unstable to temperature variation is determined from the magnitude of the measurement change. It is inherent in the method taught by Garver et al that the instability of the colloid sample analyzed is manifested by particle agglomeration due to the reduction in the height of the potential energy barrier between the particles since Garver et al teach that the particles in the colloid sample undergo phase transition due to the change in the temperature applied, and the measurements of light attenuation and light scattering serve to give an overall particle distribution of colloidal components (i.e. agglomerated particles) therein. See the abstract, lines 55-66 in column 8 and lines 32-35 in column 9 of Garver et al.

5. Claims 1-10, 13, 47-59 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicoli et al (from American Laboratory, vol. 33(1), January 2001, pages 32-39).

Nicoli et al teach of a method and apparatus for measuring the stability of colloidal suspensions (dispersions of solid or liquid particles suspended in a liquid carrier). Nicoli et al teach that the stability of colloidal suspensions can be analyzed by applying a stress factor to the suspension, such as the addition of excessive amounts of electrolyte to the suspension or by thermal or pH shock (i.e. changing the temperature or pH of the suspension). See the last column on page 34 and the first column on page 39 of Nicoli et al. Nicoli et al teach that these

Art Unit: 1743

stress factors cause particles in the suspensions to coalesce or agglomerate due to the reduction in the inter-particle electrostatic repulsive forces that confer stability to the emulsion. See the middle column on page 34 of Nicoli et al. Nicoli et al teach that the particle size distribution of a colloidal suspension can be measured by analyzing the suspension with a single particle optical sensor (SPOS), which serves to measure both the light diffraction and light scattering of the sample. The technique of single particle optical sensing provides sensitivity to small changes in the large-particle fraction of a colloidal suspension. This sensitivity is required to ascertain the quality and stability of a product. The SPOS technique analyzes particles one at a time to produce a particle size distribution that is constructed directly from each particle. Each particle traverses a flow channel through a ribbon of light. The sensor responds to the particles by measuring both light scattering and light extinction. See page 36 in Nicoli et al. The particle size distribution (PSD) produced includes the concentration of particles as a function of size over a range of normal particle sizes and a distribution of outlier particles comprising the uppermost tail of the PSD. The outlier particles in the tail of the PSD consist of oversized fat globules caused by coalescence of the smaller primary droplets due to reduction of the inter-droplet electrostatic repulsive forces that confer stability to the emulsion.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1743

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11-12, 14, 18-22, 29-33, 37-40, 60-61, 63 and 67-71 are rejected under 35

U.S.C. 103(a) as being unpatentable over Nicoli et al (from American Laboratory).

For a teaching of Nicoli et al, see previous paragraphs in this Office action.

Nicoli et al fail to teach that changing the pH level or adding electrolyte to a colloidal suspension serves to change or reduce the net charge on the surfaces of the particles in the suspension. However, such a phenomenon would have been obvious to one of ordinary skill in the art at the time of the instant invention since Nicoli et al teach that the stress factors such as pH shock and addition of electrolyte to a colloidal suspension serve to change and reduce the electrostatic repulsion between the particles, thus indicating a change or reduction of the net charge on the surfaces of the particles. Nicoli et al also fail to teach of applying the stress factors to a colloidal suspension in increments at spaced time intervals resulting in increasingly higher stress levels, or of applying different levels of stress factor to different batches of the same colloidal suspension. However, these steps would have been obvious to one of ordinary skill in the art in order to analyze and determine what level of stress factor is required to cause a colloidal suspension to become unstable, and how long/what level of the stress factor must be applied to the colloidal suspension in order to render it unstable. Nicoli et al also fail to teach of

Art Unit: 1743

calculating the percentage of the dispersed phase (PDP) in the colloidal suspension analyzed from the measured particle size distribution. However, such a step would have been obvious to one of ordinary skill in the art in order to obtain a measure of the stability of the suspension since the greater the percentage of dispersed particles in the suspension, the greater the stability and vice-versa.

9. Claims 15-17, 34-36 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicoli et al (from American Laboratory) in view of Friberg et al (submitted in the Information Disclosure Statement filed on September 24, 2003). For a teaching of Nicoli et al, see previous paragraphs in this Office action. Nicoli et al fail to teach that that addition of a salt to a colloidal suspension can be used as a stress factor to measure the stability of the suspension.

Friberg et al teach that the addition of an electrolyte or salt such as sodium chloride to an emulsion causes a reduction in the electric repulsion potential of the particles in the emulsion, and a resulting reduction in the barrier height between the particles. This change with salt concentration results in a loss of stability in the emulsion due to the agglomeration of the particles therein. Friberg et al teach that the change from a stable emulsion to an unstable one takes place at a well-defined salt concentration. See the last half of page 66 in Friberg et al.

Based upon the combination of Nicoli et al and Friberg et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to perform the stability testing method taught by Nicoli et al by adding a salt such as sodium chloride to a colloidal suspension as the stress factor since Friberg et al teach that the addition of a salt to an emulsion serves to render the emulsion unstable by reducing the repulsion potential and the barrier height

Art Unit: 1743

between the particles, similar to the action of changing the pH or adding an electrolyte to the colloidal suspension.

10. Claims 23-28, 41-46 and 72-77 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a method and apparatus for measuring the stability of a colloidal suspension by applying a stress factor to the suspension, measuring the level of particle agglomeration in the suspension, and calculating a rate of change or an increase of a percentage of the dispersed phase (PDP) in the suspension along with a figure of merit (FM) derived from the calculated rate of change or increase in the PDP.

11. Applicant's arguments filed April 18, 2005 have been fully considered but they are not persuasive.

Most of the previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on November 16, 2004 have been withdrawn in view of Applicants' amendments to the claims. However, a few rejections under this statute remain as noted above in paragraph no. 1.

Applicants argue the rejection of the claims under 35 USC 102(b) as being anticipated by Garver et al by stating that Garver et al do not teach of applying a "stress factor" to an emulsion or dispersion in the same way as the instant invention, and that Garver et al do not teach or suggest reducing a height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration. Applicants argue that in Garver et al, a temperature-induced phase transition of colloidal particles is performed in order to detect an amount of

Art Unit: 1743

colloidal pitch in an emulsion, and that Garver et al do not teach of a method that gently destabilizes an emulsion by systematically reducing the potential energy barriers between particles with an incremental increase in application of a stress factor to the emulsion over time.

In response to these arguments, it is first noted that Garver et al is used to reject only instant claims 1, 8, 47 and 54 which broadly recite a method and apparatus for determining the stability of a sample comprising a dispersion of solid or liquid droplets suspended in a liquid carrier by applying a stress factor to the sample to reduce the height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration in the sample, and detecting an increase in the particle agglomeration. These claims do not recite systematically applying a stress factor to the sample in increasing increments over time, and analyzing different levels of particle agglomeration with each incremental stress factor level. Therefore, this argument by Applicants is not found persuasive since it is not pertinent to the claims rejected under 35 USC 102(b) using Garver et al as a reference.

Secondly, it is noted on pages 17-20 of the instant specification in the “background of the specification” that it is known in the art to apply a “thermal stress” to an emulsion or dispersion in order to test the stability of the emulsion or dispersion. One of the prior art references teaching such a method included in the discussion on pages 17-20 is Garver et al. These pages of the specification indicate that it is known that an increase in temperature applied to an emulsion or dispersion causes diminished stability in the emulsion or dispersion due to a decrease in the interparticle potential energy barrier height between particles in the emulsion or dispersion. The decreased interparticle potential energy barrier height between the particles in the emulsion or dispersion causes the particles to agglomerate together. Pages 17-20 of the

Art Unit: 1743

instant specification further note that it is known in the prior art to perform particle size analysis on the emulsions stressed with an increased temperature in order to obtain a particle size distribution (PSD) and detect large agglomerates of particles. In view of this known information outlined in the "background of the invention" section of the specification and the fact that the teaching of Garver et al represents one of the known prior art thermal stress tests for evaluating the stability of an emulsion or dispersion, the Examiner maintains the position that the teaching of Garver et al inherently discloses a method and apparatus for determining the stability of a dispersion containing liquid or solid droplets in a liquid carrier, as outlined in instant claims 1, 8, 47 and 54, since the disclosure of Garver et al teaches of applying a stress factor to a dispersion (i.e. a temperature increase), and detecting an increase in particle agglomeration as a result of the thermal stress factor by a measurement of light attenuation or scattering. Since the background of the specification indicates that a thermal stress factor applied to an emulsion serves to decrease the interparticle potential energy barrier height between particles in the emulsion, this action inherently occurs in the method taught by Garver et al. The increased temperature to which the emulsion in Garver et al is exposed to can be considered a "stress factor" as defined by Applicants because it serves to destabilize an emulsion by decreasing the interparticle potential energy barrier height between the particles in the emulsion in the same way as the application of an acid, base, electrolyte or salt to the emulsion in the instant invention. The temperature-induced phase transition of colloidal particles in the method of Garver et al is merely a symptom of instability in the emulsion that is manifested by the agglomeration of particles therein due to the decrease in the interparticle potential energy barrier height between the particles.

Applicants argue the rejection of the claims under 35 USC 102(b) and 35 USC 103 as being anticipated by or obvious in view of Nicoli et al by stating that Nicoli et al only teach of ascertaining the quality of a dispersion, not the stability by determining the rate of particle agglomeration increase due to a decrease in particle barrier height. In response to this argument, it is noted that Nicoli et al repeatedly refer to the stability of a dispersion in combination with its quality by measuring the amount of agglomerated fat globules caused by coalescence of smaller primary droplets in the dispersion due to reduction of the interdroplet electrostatic repulsive forces that confer stability to the emulsion. See the middle column on page 34 of Nicoli et al. Therefore, Nicoli et al do teach of measuring the stability of emulsions or dispersions since the greater the concentration of large aggregates found in the outlier tail portion of a measured particle size distribution of the sample, the less stable the emulsion is because the presence of many large aggregates indicates that the electrostatic repulsive forces between the particles that keep an emulsion stable have been reduced.

Applicants argue that Nicoli et al fail to teach of using graduated, systematic stressing of a sample and subsequent measurement of stability as a function of time or stress level. However, these steps are not recited in the instant claims presently rejected under 35 USC 102(b) as being anticipated by Nicoli et al.

Applicants argue that Nicoli et al do not teach of a method for deliberately and controllably applying a stress factor to a sample in order to reduce a height of an interparticle potential energy barrier so as to accelerate the onset of particle agglomeration. Contrary to Applicants' argument, Nicoli et al do teach of a deliberately destabilizing an emulsion by the addition of excessive amounts of amino acids or electrolytes to a fat emulsion. See the first

Art Unit: 1743

column on page 39 and Figure 4 of Nicoli et al. The particle size distribution of the destabilized fat emulsion is measured as a function of elapsed time in order to determine the concentration and mean size of oversize fat globules in the outlier tails of the distribution.

Applicants argue that Nicoli et al do not teach of different levels of stress applied to a dispersion over time. However, Nicoli et al do teach of measuring the destabilization of an emulsion with elapsed time due to the application of a stress factor (i.e. amino acids or electrolytes). See Figure 4 and page 39 in Nicoli et al. It would have been obvious to one of ordinary skill in the art to apply different levels of amino acids or electrolytes to the fat emulsion taught by Nicoli et al in order to analyze and determine what level of stress factor is required to cause a colloidal suspension to become unstable as manifested by a certain degree of particle agglomeration.

Applicants argue that Nicoli et al fail to teach of determining the rate of change of PDP (percentage of dispersed particles) with elapsed time or the rate of change of the PDP with increasing stress level. This argument is found persuasive as indicated by the allowability of dependent claims 23-28, 41-46 and 72-77 noted above. However, the simple measurement of PDP in the emulsions taught by Nicoli et al would have been obvious to one of ordinary skill in the art in order to determine what percentage of the aggregated particles in the oversize outlier aggregates taught by Nicoli et al contribute to the overall number of colloidal particles dispersed in the liquid phase of the emulsion.

Applicants argue that the reference to Friberg et al applied against the claims under 35 USC 103 does not teach of the controlled application of stress levels to emulsion systems having different rates of particle agglomeration. In response to this argument, it is noted that Friberg et

Art Unit: 1743

al is not used as a primary reference to teach a method for determining the stability of an emulsion, but rather, it is used as a secondary teaching that the addition of electrolytes and salts to an emulsion causes a reduction in the electric repulsive potential between the particles in an emulsion, thus resulting in a loss of stability of the emulsion by allowing the particles to move closer to one another and aggregate.

For all of the above reasons, Applicants' arguments are not found persuasive.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1743

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 28, 2005

Maureen M. Wallenhorst
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PRIMARY EXAMINER
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